



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: STUYVER, et al.

Serial No.: 10/008,140

Filed: OCTOBER 18, 2001

Title: Simultaneous Quantification of Nucleic Acids in Diseased Cells

Assistant Commissioner for Patents  
Washington, DC 20231

March 22, 2002

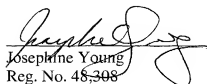
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STATEMENT BY APPLICANT**

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Sheet **6** of **7****Complete if Known**

Application Number	10/008,140
Filing Date	OCTOBER 18, 2001
First Named Inventor	LIEVEN STUYVER, et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number	08841.105021 (PHAR 1040U)

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	CA	OBERST, R.D., et al., PCR-Based DNA Amplification and Presumptive Detection of <i>Escherichia coli</i> O157:H7 with an Internal Fluorogenic Probe and the 5' Nuclease (TaqMan) Assay, <i>Applied and Environmental Microbiology</i> , Sept. 1998, 64:3389-3396.	
	CB	OHYASHIKI, J.H., et al. Use of Real-Time PCR to Monitor Human Herpesvirus 6 Reactivation After Allogeneic Bone Marrow Transplantation, <i>Int. J. Mol. Med.</i> , 6:427-432.	
	CC	PE APPLIED BIOSYSTEMS, User Bulletin #2 ABI PRISM 7700 Sequence Detection System, December 11 1997, 1-36.	
	CD	PEVENSTEIN, S. R., et al., Quantitation of Latent Varicella-Zoster Virus And Herpes Simplex Virus Genomes in Human Trigeminal Ganglia, <i>J. Virol.</i> , Dec. 1999, 73:10514-10548.	
	CE	RATGE, D., et al., High-Speed Detection of Blood-Borne Hepatitis C Virus RNA by Single-Tube Real-Time Fluorescence Reverse Transcription-PCR With the LightCycler, <i>Clin. Chem.</i> , 2000, 46:1987-1989.	
	CF	SAHA, B.K., et al. Quantitation of HIV-1 by Real-Time PCR With a Unique Fluorogenic Probe, <i>J. Virol. Methods</i> , 2001, 93:33-42.	
	CG	SAULEDA, S., et al., Profiles of GBV-C/hepatitis G virus Markers in Patients Coinfected With Hepatitis C Virus, <i>J. Med. Virol.</i> , 1999, 59:45-51.	
	CH	SCHUTTEN, M., et al., Development of a Real-Time Quantitative RT-PCR for the Detection of HIV-2 RNA in Plasma, <i>J. Virol. Methods</i> , 2000, 88:81-87.	
	CI	SOKOL, D.L., et al., Real Time Detection of DNA-RNA Hybridization in Living Cells, <i>Proc. Natl. Acad. Sci. USA</i> , Sept. 1998, 95:11538-11543.	
	CJ	SURYANARAYANA, K., et al., Plasma SIV RNA Viral Load Determination by Real-Time Quantification of Product Generation in Reverse Transcriptase-Polymerase Chain Reaction, <i>AIDS Res. Hum. Retroviruses</i> , 1998, 14:183-189.	

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	CK	SWAN, D.C., et al. A Sensitive, Type-Specific, Fluorogenic Probe Assay for Detection of Human Papillomavirus DNA, <i>J. Clin. Microbiol.</i> , 1997, 35:886-891.	
	CL	TAKEUCHI, T., et al. Real-Time Detection System for Quantification of Hepatitis C Virus Genome, <i>Gastroenterology</i> , 1999, 116:636-642.	
	CM	TANAKA, N., et al. Quantitative Analysis of Cytomegalovirus Load Using a Real-Time PCR Assay, <i>J. Med. Virol.</i> , 2000, 60:455-462.	
	CN	TAPP, L., et al., Homogenous Scoring of Single-Nucleotide Polymorphisms: Comparison of the 5'-Nuclease TaqMan® Assay and Molecular Beacon Probes, <i>BioTechniques</i> , 2000, 28:732-738.	
	CO	TYAGI, S., et al., Multicolor Molecular Beacons For Allele Discrimination, <i>Nature Biotechnology</i> , Jan. 1998, 16:49-53.	
	CP	TYAGI, S., et al., Molecular Beacons: Probes That Fluoresce Upon Hybridization, <i>Nat. Biotechnol.</i> , 1996, 14:303-308.	
	CQ	VAN ELDEN, L.J.R., et al., Simultaneous Detection of Influenza Viruses A and B Using Real-Time Quantitative PCR, <i>J. Clin. Microbiol.</i> , Jan. 2001, 39:196-200.	
	CR	VET, J.A.M., et al., Multiplex Detection of Four Pathogenic Retroviruses Using Molecular Beacons, <i>Proc. Natl. Acad. Sci. USA</i> , May 1999, 96:6394-6399.	
	CS	WAGNER, H. J., et al., Real-Time Polymerase Chain Reaction (RQ-PCR) for the Monitoring of Epstein-Barr Virus (EBV) Load in Peripheral Blood Mononuclear Cells, <i>Klin. Padiatr.</i> , 2000, 212:206-210.	
	CT	WALKER, N.J., et al., Real-Time And Quantitative PCR: Applications to Mechanism-Based Toxicology, <i>J. Biochem. Mol. Toxicol.</i> , 2001, 15:121-127.	
	CU	WHITE, I.E., et al. Quantitation of Cell-Free and Cell-Associated Kaposi's Sarcoma-Associated Herpesvirus DNA by Real-Time PCR, <i>J. Clin. Microbiol.</i> , May 2000, 38:1992-1995.	

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	BG	KUIMELIS, R. G., et al., Structural Analogues of TaqMan Probes for Real-Time Quantitative PCR, <i>Nucleic Acids Symp. Ser. No. 37</i> , 1997, 37:255-256.	
	BH	LALLEMAND, F., et al., Quantitative Analysis of Human Herpesvirus 8 Viral Load Using a Real-Time PCR Assay, <i>J. Clin. Microbiol.</i> April 2000, 38:1404-1408.	
	BI	LEONE, G., et al., Molecular Beacon Probes Combined With Amplification by NASBA Enable Homogenous, Real-Time Detection of RNA, <i>Nucleic Acids Research</i> , 1998, 26:2150-2155.	
	BJ	LEWIN, S. R., et al. Use of Real-Time PCR and Molecular Beacons to Detect Virus Replication in Human Immunodeficiency Virus Type 1-Infected Individuals on Prolonged Effective Antiretroviral Therapy, <i>J. Virol.</i> , July 1999, 73:6099-6103.	
	BK	LIVAK, K.J., et al., Oligonucleotides With Fluorescent Dyes at Opposite Ends Provide a Quenched Probe System Useful for Detecting PCR Product and Nucleic Acid Hybridization, <i>PCR Methods</i> , 1995, 4:357-362.	
	BL	LOCATELLI, G., et al. Real-Time Quantitative PCR for Human Herpesvirus 6 DNA, <i>J. Clin. Microbiol.</i> , Nov. 2000, 38:4042-4048.	
	BM	LOCKEY, C., et al., Real-Time Fluorescence Detection of a Single DNA Molecule, <i>Biotechniques</i> , May 1998, 24:744-746.	
	BN	MACHIDA, U., et al., Real-Time Automated PCR For Early Diagnosis and Monitoring of Cytomegalovirus Infection After Bone Marrow Transplantation, July 2000, <i>J. Clin. Microbiol.</i> , 38:2536-2542.	
	BO	MARCUCCI, G., et al. Detection of Minimal Residual Disease in Patients With AML1/ETO-Associated Acute Myeloid Leukemia Using a Novel Quantitative Reverse Transcription Polymerase Chain Reaction Assay, <i>Leukemia</i> , 1998, 12:1482-1489.	
	BP	MARRAS, S.A.E., et al., Multiplex Detection of Single-Nucleotide Variations Using Molecular Beacons, <i>Genetic Analysis: Biomolecular Engineering</i> , 1999, 14:151-156.	

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	AK	CANE, P.A., et al. Use of real-time PCR and fluorimetry to detect lamivudine resistance-associated mutations in hepatitis B virus., <i>Antimicrobial Agents and Chemotherapy</i> . July 1999, 43:1600-1608.	
	AL	CUBIE, H.A., et al. Rapid real time PCR to distinguish between high risk human papillomavirus types 16 and 18. <i>Mol Pathol</i> . 2001, 54:24-29.	
	AM	DE KOK J.B., Hendriks JCM, van Solinge WW, Willems HL, Mensink EJ, Swinkels DW. Use of real-time quantitative PCR to compare DNA isolation methods. <i>Clin Chem</i> 1998;44:2201-2204.	
	AN	DÉSIRÉ, N., et al. Quantification of human immunodeficiency virus type 1 proviral load by a TaqMan real-time PCR assay. <i>J Clin Microbiol</i> . 2001, 39:1303-1310.	
	AO	ENGER, L., et al. Cloning and Characterization of a Complex DNA Fingerprinting Probe for <i>Candida parapsilosis</i> . <i>J. Clin. Microbiol</i> . Feb. 2001, 39:658-669.	
	AP	GAULT, E., et al. Quantification of Human Cytomegalovirus DNA by Real-Time PCR. <i>J Clin Microbiol</i> . Feb. 2001, 39:772-775.	
	AQ	GELMINI, S., et al. Quantitative polymerase chain reaction-based homogeneous assay with fluorogenic probes to measure <i>c-erbB-2</i> oncogene amplification. <i>Clin Chem</i> 1997, 43:752-758.	
	AR	GERARD, C.J., et al. Improved Quantitation of Minimal Residual Disease in Multiple Myeloma Using Real-Time Polymerase Chain Reaction and Plasmid-DNA Complementarity Determining Region III Standards. <i>Cancer Res</i> Sept. 1998; 58:3957-3964.	
	AS	GIBSON, U.E.M., et al. A Novel Method For Real-Time Quantitative RT-PCR. <i>Genome Res</i> 1996, 6:995-1001.	
	AT	GIESENDORF, B.A.J., et al. Molecular Beacons: A New Approach For Semiautomated Mutation Analysis. <i>Clin. Chem</i> . 1998, 44:482-486.	

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	AU	GRUBER, F., et al. Quantitation of Viral DNA By Real-Time PCR Applying Duplex Amplification, Internal Standardization, and Two-Color Fluorescence Detection. <i>Appl Environ Microbiol.</i> 2001, 67:2837-2839.	
	AV	HEID, C.A., et al. Real-Time Quantitative PCR. <i>Genome Research</i> , 1996; 6:986-994.	
	AW	HOLLAND, P.M., et al. Detection of Specific Polymerase Chain Reaction Product By Utilizing the 5'-3' Exonuclease Activity of Thermus Aquaticus DNA Polymerase. <i>Proc Natl Acad Sci USA</i> , 1991;88:7276-7280.	
	AX	JABS, W. J., et al., Normalized Quantification by Real-Time Per of Epstein-Barr Virus Load in Patients at Risk for Posttransplant Lymphoproliferative Disorders. <i>J Clin Microbiol.</i> 2001, 39:564-569.	
	AY	JOSEFSSON, A., et al., Detection and Quantitation of Human Papillomavirus by Using the Fluorescent 5' Exonuclease Assay. <i>J. Clin. Microbiol.</i> , March 1999, 37:490-496.	
	AZ	JU, J., et al. Fluorescence Energy Transfer Dye-Labeled Primers for DNA Sequencing and Analysis. <i>Proc. Natl. Acad. Sci. USA</i> , May 1995, 92:4347-4351.	
	BA	KATO, T., et al. Development of a TT Virus DNA Quantification System Using Real-Time Detection PCR. <i>J. Clin. Microbiol.</i> , Jan. 2000, 38:94-98.	
	BB	KEARNS, A. M., et al. Development and Evaluation of a Real-Time Quantitative PCR for the Detection of Human Cytomegalovirus. <i>J. Virol. Methods</i> , 2001, 95:121-131.	
	BC	KESSLER, H. H., et al. Detection of Herpes Simplex Virus DNA by Real-Time PCR. <i>J. Clin. Microbiol.</i> , 2000, 38:2638-2642.	
	BD	KIMURA, H., et al. Quantitative Analysis of Epstein-Barr Virus Load by Using a Real-Time PCR Assay. <i>J. Clin. Microbiol.</i> , Jan. 1999, 37:132-136.	
	BE	KOMURIAN-PRADEL, F., et al., Quantitation of HCV RNA Using Real-Time PCR and Fluorimetry. <i>J. Virol. Methods</i> , 2001, 95:111-119.	
	BF	KOSTRIKIS, L.G., et al., Spectral Genotyping of Human Alleles, <i>Science</i> , Feb. 1998, 279:1228-1229.	

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		Number	Kind Code <sup>2</sup> (if known)			
	AA	5,843,640		PATTERSON, et al.	12-01-1998	
	AB	6,210,875		PATTERSON, et al.	04-03-2001	
	AC	6,235,504		ZHANG, et al.	05-22-2001	

### FOREIGN PATENT DOCUMENTS

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	AD	WO	00/44936	Commissariat a l'energie	08-03-2000		
	AE	WO	00/68436	BOSBACH, et al.	11-16-2000		
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	AG	ABE, A., et al. Quantitation of hepatitis B virus genomic DNA by real-time detection PCR. <i>J Clin Microbiol.</i> Sept. 1999, 37:2899-2903.			
	AH	ABERHAM, C., et al. A quantitative, internally controlled real-time PCR Assay for the detection of parvovirus B19 DNA. <i>J Virol Methods.</i> 2001, 92:183-191.			
	AI	BISSET, L. R., et al. Quantification of in vitro retroviral replication using a one-tube real-time RT-PCR system incorporating direct RNA preparation. <i>J Virol Methods.</i> 2001, 91:149-155.			
	AJ	BONNET, G., et al. Thermodynamic basis of the enhanced specificity of structured DNA probes. <i>Proc. Natl. Acad. Sci. USA.</i> May 1999, 96:6171-6176.			

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Sheet **5** of **7****Complete if Known**

Application Number	<b>10/008,140</b>
Filing Date	<b>OCTOBER 18, 2001</b>
First Named Inventor	<b>LIEVEN STUYVER, et al.</b>
Group Art Unit	
Examiner Name	
Attorney Docket Number	<b>08841.105021 (PHAR 1040U)</b>

**OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. †	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	BQ	MARTELL, M., et al. High-Throughput Real-Time Reverse Transcription-PCR Quantitation of Hepatitis C Virus RNA. <i>J. Clin. Microbiol.</i> , Feb. 1999, 37:327-332.	
	BR	MATSUO, T., In Situ Visualization of Messenger RNA for Basic Fibroblast Growth Factor in Living Cells, <i>Biochimica et Biophysica Acta</i> , 1998, 1379:178-184	
	BS	MCGOLDRICK, A., et al, A Novel Approach To The Detection of Classical Swine Fever Virus by RT-PCR With a Fluorogenic Probe (TaqMan), <i>J. Virol. Methods</i> , 1998, 72:125-135.	
	BT	MORRIS, T., et al. Rapid Reverse Transcription-PCR Detection of Hepatitis C Virus RNA in Serum by Using the TaqMan Fluorogenic Detection System, <i>J. Clin. Microbiol.</i> , Dec. 1996, 34:2933-2936.	
	BU	NAJIOULLAH, F., et al., Development of a Real-Time PCR Procedure Including an Internal Control for the Measurement of HCMV Viral Load. <i>J. Virol. Methods</i> , 2001, 92:55-64.	
	BV	NAZARENKO, I.A., et al., A Closed Tube Format for Amplification and Detection of DNA Based on Energy Transfer, <i>Nucleic Acids Research</i> , 1997, 25:2516-2521.	
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	BX	NIESTERS, H.G.M., et al., Development of a Real-Time Quantitative Assay for Detection of Epstein-Barr Virus, <i>J. Clin. Microbiol.</i> , Feb. 2000, 38:712-715.	
	BY	NITSCHKE, A., et al., Detection of Human Cytomegalovirus DNA by Real-Time Quantitative PCR, <i>J. Clin. Microbiol.</i> , July 2000, 38:2734-2737.	
	BZ	NUOVO, G.J., et al, In Situ Amplification Using Universal Energy Transfer-Labeled Primers, <i>J. Histochem. &amp; Cytochem.</i> , 1999, 43:273-279.	

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